



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,694	01/24/2002	Stephane Gobron	CL/V-31975A	1035

31781 7590 09/29/2004

CIBA VISION CORPORATION
PATENT DEPARTMENT
11460 JOHNS CREEK PARKWAY
DULUTH, GA 30097-1556

EXAMINER

MAYES, MELVIN C

ART UNIT	PAPER NUMBER
----------	--------------

1734

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,694	GOBRON ET AL.	
	Examiner	Art Unit	
	Melvin Curtis Mayes	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) 38-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 10, 13-24 and 32-37 is/are rejected.
- 7) ☒ Claim(s) 5-8, 11, 12 and 25-31 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/20/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

(1)

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-46, drawn to a method for molding an ophthalmic lens, classified in class 264, subclass 1.32.
- II. Claim 47, drawn to an apparatus for molding a polymer, classified in class 425, subclass 808.

(2)

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used with a polymer which is exposed to radiation for curing while between the mold parts.

(3)

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

(4)

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 1-37 directed to a melt-processable polymer

Claims 38-46 directed to reactive pre-polymer.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

(5)

During a telephone conversation with Jian Zhou on September 17, 2004, a provisional election was made without traverse to prosecute the invention of claims 1-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 38-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

(6)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

(7)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(8)

Claims 35-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Yang et al. 6,042,754.

Yang et al. discloses a method for making ophthalmic lenses comprising: providing a lower die (first mold part) and top die (second mold part) of a die set; extruding a polymer material to form a strand of melt from a polymer feeder using any suitable extruder; feeding the melt extrudate onto the lower die; cutting the melt extrudate by the edge of the upper die; feeding the top die on top of the melt; pressing the die set at a predetermined pressure; separating the die set; ejecting the lens from the die set; and recycling the die set for reuse to form additional lenses. The die set is pressed to a predetermined die set cavity gap height and held for effective time (5-15 seconds) to solidify the polymer. The quantity of the melt added to the die is the exact amount needed and the die set has not escape gate for the melt but only air is vented out (col. 3-12).

Claim Rejections - 35 USC § 103

(9)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1734

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(10)

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. 6,042,754.

Yang et al. discloses a method for making ophthalmic lenses comprising: providing a lower die (first mold part) and top die (second mold part) of a die set; extruding a thermoplastic polymer material to form a strand of melt from a polymer feeder using any suitable extruder; feeding the melt extrudate onto the lower die; cutting the melt extrudate by the edge of the upper die; feeding the top die on top of the melt; pressing the die set at a predetermined pressure; separating the die set; ejecting the lens from the die set; and recycling the die set for reuse to

form additional lenses. The polymer can contain a small amount of crosslinking agent so that the lens will not be completely re-fusible. The dies of the die set are preferable preheated to a temperature 20°C higher than the T_g of the polymer and 10°C lower than the decomposition temperature of the polymer. The quantity of the melt added to the die is only slightly more than the quantity needed (about 1-10 wt% excess) or is the exact amount needed and the die set has no escape gate for the melt but only air is vented out. The melt strand has a circular cross section (col. 3-12).

By feeding and cutting melt extrudate in the exact amount needed into a lower die of a die set which has no escape gate for the melt but only allows air to be vented out, a sample cut from an extruded melt-processable polymer is obviously deposited in the first mold part which with a second mold part form a mold cavity having a variable volume between first and second volume, the mold parts having clearance such that gas escapes from the mold cavity but none of the polymer escapes, as claimed.

(11)

Claims 2, 3, 9, 15-22, 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. as applied to claim 1 above, and further in view of Hammar et al. 4,673,539.

Yang et al. disclose extruding using any suitable extruder and disclose that the polymer can contain a small amount of crosslinking agent so that the lens will not be completely re-fusible. The dies of the die set are preferable preheated to a temperature 20°C higher than the T_g of the polymer and 10°C lower than the decomposition temperature of the polymer and after pressing the temperature is gradually lowered to room temperature. The quantity of the melt

Art Unit: 1734

added to the die is only slightly more than the quantity needed (about 1-10 wt% excess) or is the exact amount needed and the die set has no escape gate for the melt but only air is vented out.

Hammar et al. teach that hydrogels have desirable properties useful as contact lens material, however, hydrogels are generally non-thermoplastic and not moldable into shaped articles. Hammar et al. teach that ophthalmic devices, such as contact lens, of improved structural integrity and improved strength can be made from a thermally processable polymer which is a precursor to a hydrogel. After thermoforming the polymer in a mold, the polymer is solvolyzed then hydrated to provide a shaped hydrogel article (col. 1- col. 4, line 20).

It would have been obvious to one of ordinary skill in the art to have modified the method of Yang et al. for making an ophthalmic lens by providing the thermoplastic polymer material as a hydrophilic thermoplastic precursor to a hydrogel, as taught by Hammar et al., as desirable for making contact lens of improved structural integrity and improved strength compared to using a non-thermoplastic. Hydrating and packing the lens after removing from the die set (mold) would have been obvious to one of ordinary skill in the art, as Hammar et al. teach that after thermoforming a thermally processable polymer precursor to a hydrogel, the polymer is hydrated to provide a shaped hydrogel article. Packaging is well known in the art as conventional for contact lens after molding and hydrating.

Using an extruder having a melt pump and closed-loop pressure feedback control system, as claimed in Claims 15 and 16, would have been obvious to one of ordinary skill in the art as a suitable extruder that can be used to extrude the polymer.

(12)

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 22 above, and further in view of Yang et al. 6,015,512.

Yang et al. teach that mold dies for making thermoplastic optical articles are cleaned in distilled water and dried before use for molding (col. 9, lines 5-6).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by cleaning the lower and top dies after molding, as taught by Yang et al., to process the dies for reuse for molding.

(13)

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 2 above, and further in view of Yamanaka et al. 6,099,765.

Yamanaka et al. teach that funnel-shaped holding pad formed of silicon rubber and connected to a vacuum source for holding optical material to the holding pad is used to hold optical material when moving it into and away from the mold apparatus (col. 4, lines 17-25).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by using a silicon rubber pad and vacuum to separate the lens from the dies, as taught by Yamanaka et al., as known for use to hold optical material when moving it away from the mold apparatus.

(14)

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruhlin 5,100,590 in view of Yang et al. 6,309,568.

Ruhlin discloses a method of making an ophthalmic lens comprising: providing a blank of thermoplastic synthetic material by cutting or stamping from a plate or rod; placing the blank in a mold having a lower molding surface and upper molding surface of shell members having a circular peripheral contour reflecting that of the blank and complementary to those required of the ophthalmic lens, the shell members fitted in a ring which completes the mold with just sufficient annular clearance for the molding shell members to slide freely inside the ring; placing the mold in an oven; applying molding force to the blank by a pre-load mass in the order of 1 kg; separating the molding shell members from the blank; and reusing the shell members in a new working cycle. The finished lens can have a thickness at the edge in the order of 1.5 mm and thickness at the center in the order of 2 mm (col. 2, line 30 – col. 5, line 12). Ruhlin does not disclose cutting the blank from an extruded plate or rod.

Yang et al. teach that in making an lens from a thermoplastic material, the material is extruded in a sheet-like shape from which a lens precursor such as of disc shape is punched for placement in the press machine. Yang et al. further teach that a thermoplastic thiourethane-urethane copolymer having a T_g of 116°C is extruded at about 190°C and is gradually cooled upon being extruded (col. 2, lines 50-59, col. 4, lines 4-15).

It would have been obvious to one of ordinary skill in the art to have modified the method of Ruhlin for making an ophthalmic lens by providing the plate or rod from which the

blank is cut by extruding, as taught by Yang et al., for providing a shape of thermoplastic material from which a lens precursor is punched (cut) for subsequent molding.

By molding the thermoplastic blank in a mold in which the shell members fitted in a ring which completes the mold with just sufficient annular clearance for the molding shell members to slide freely inside the ring, a sample cut from an extruded melt-processable polymer is obviously deposited in the first mold part which with a second mold part form a mold cavity having a variable volume between first and second volume, the mold parts having clearance such that gas escapes from the mold cavity but none of the polymer escapes, as claimed.

(15)

Claims 2-4, 10, 13, 14, 17, 18, 22, 24 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruhlin 5,100,590 in view of Yang et al. 6,309,568 as applied to claim 1 above, and further in view of Hammar et al. 4,763,539.

Ruhlin discloses that the finished lens can have a thickness at the edge in the order of 1.5 mm and thickness at the center in the order of 2 mm.

Yang et al. further teach that a thermoplastic thiourethane-urethane copolymer having a T_g of 116°C is extruded at about 190°C and is gradually cooled upon being extruded (col. 2, lines 50-59, col. 4, lines 4-15).

Hammar et al. teach that hydrogels have desirable properties useful as contact lens material, however, hydrogels are generally non-thermoplastic and not moldable into shaped articles. Hammar et al. teach that ophthalmic devices, such as contact lens, of improved structural integrity and improved strength can be made from a thermally processable polymer

which is a precursor to a hydrogel. After thermoforming the polymer in a mold, the polymer is solvolyzed then hydrated to provide a shaped hydrogel article (col. 1- col. 4, line 20).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined for making an ophthalmic lens by providing the thermoplastic polymer material as a hydrophilic thermoplastic precursor to a hydrogel, as taught by Hammar et al., as desirable for making contact lens of improved structural integrity and improved strength compared to using a non-thermoplastic. Hydrating and packing the lens after removing from the die set (mold) would have been obvious to one of ordinary skill in the art, as Hammar et al. teach that after thermoforming a thermally processable polymer precursor to a hydrogel, the polymer is hydrated to provide a shaped hydrogel article. Packaging is well known in the art as conventional for contact lens after molding and hydrating.

Extruding in the form of a wire and cutting a pellet from the wire, as claimed in Claim 4 would have been obvious to one of ordinary skill in the art, as Ruhlin discloses cutting a blank from a rod.

Extruding at temperature as claimed in Claim 13 and 14 would have been obvious one of ordinary skill in the art as Yang et al. teach extruding a thermoplastic having a T_g of 116°C at about 190°C and gradually cooling upon being extruded.

(16)

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 2 above, and further in view of Yamanaka et al. 6,099,765.

Yamanaka et al. teach that funnel-shaped holding pad formed of silicon rubber and connected to a vacuum source for holding optical material to the holding pad is used to hold optical material when moving it into and away from the mold apparatus (col. 4, lines 17-25).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by using a silicon rubber pad and vacuum to separate the lens from the mold, as taught by Yamanaka et al., as known for use to hold optical material when moving it to and away from the mold apparatus.

Allowable Subject Matter

(17)

Claims 5-8, 11, 12 and 25-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

(18)

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 1734


(19)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin Curtis Mayes whose telephone number is 571-272-1234.

The examiner can normally be reached on Mon-Fri 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on 571-272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Melvin Curtis Mayes
Primary Examiner
Art Unit 1734

MCM
September 27, 2004